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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/591,321 | 08/31/2006 | Morten Reeslev | 36731-000093/US | 9441 |
| 30593 | 7590 | 03/26/2010 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195 | | | | MARTIN, PAUL C |
| ART UNIT | | PAPER NUMBER | | |
| 1657 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|---|------------------------|---------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
| | 10/591,321 | REESLEV ET AL. |
| | Examiner | Art Unit |
| | PAUL C. MARTIN | 1657 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a) They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) They raise the issue of new matter (see NOTE below);
- (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. Applicant's reply has overcome the following rejection(s): _____.

6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Continuation Sheet.

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.

13. Other: _____.

/Rebecca E. Prouty/
Primary Examiner, Art Unit 1652

Continuation of 3. NOTE: The new limitations found in claims 59 and 60 would require a further search and/or consideration.

DETAILED ACTION

Claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-60 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Pending Claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-58 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuompo et al. (US 5,714,343) in view of Koumara et al. (US 5,591,554) for reasons of record set forth in the Prior Action.

Response to Arguments

Applicant's arguments filed 03/15/2010 have been fully considered but they are not persuasive.

The Applicant argues that nothing in the Tuompo et al. reference implies that MTT should be detected in the test solution on the effluent side of the filter. That is, detection could be performed by analysis of the filter or the liquid on the influent side of the filter. Applicant cites portions of the reference stating that NBT is the preferred chromogenic reagent and that NBT is advantageous over MTT because the color can be deposited on a restricted area of the filter because it precipitates at a point where the dehydrogenases are situated around the bacteria (Remarks, Pg. 15, Lines 4-13).

This is not found to be persuasive for the following reasons, the Tuompo et al. reference teaches the use of the soluble chromogenic substrate MTT in the detection of filter entrapped bacteria and suggests that the water soluble MTT which is not entrapped on the filter may be detected via spectrophotometric methods in the liquid vehicle. While MTT may not be the preferred embodiment of the reference, it is nevertheless valid for its teachings in view of what would be obvious to those of ordinary skill in the art at the time of the invention. That is, that one of ordinary skill in the art would find it obvious to separate a chromogenic substrate from the filter-entrapped bacteria prior to analysis. The MPEP states:

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

The Applicant argues that in the examples provided by the reference, the cells are counted directly on the filter and that small amounts of the test solution including the chromogenic agent are used. Applicant asserts that Tuompo et al. does not suggest the use of larger volumes of test solution which would be needed in order to perform detection on any test solution that passes through the filter (Remarks, Pg. 15, Lines 14-18).

This is not found to be persuasive for the following reasons, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., large volumes of test solution including the chromogenic agent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Applicant's own claims are directed to the detection of the detectable moiety in picomolar amounts which would seem to negate the need for large liquid vehicle volumes.

The assertion that the reference is inoperable because the "small" amounts of test solution including the chromogenic detection moiety would not substantially pass through the filter is unsubstantiated by any evidentiary support. The MPEP states:

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)

The Applicant argues that the Koumara et al. reference is directed to a method for detecting microorganism and does not use a filter, and that is using the larger volumes of test reagent as taught by Koumara et al. the reference teaches the centrifugation to separate contaminants from the test reagent whereas if using the smaller volumes taught by Tuompo et al. one would allegedly inspect the filter directly and thus combination of the references does not lead one to perform steps d) and e) as claimed (Remarks, Pg. 15, Lines 19-25 and Pg. 16, Lines 1-2).

This is not found to be persuasive for the following reasons, as discussed in the Prior Action the Koumara et al. reference was only brought in for its teachings related to the detection of viable microorganisms in a liquid medium with 4-MUG substrates hydrolysable by characteristic enzymes of the microorganisms and not for any teachings of reagent volumes. As discussed above, there are no claim limitations directed to liquid volumes and speculation on the part of the Applicant that differences in liquid volumes would somehow render the combination of the two references inoperable is unsupported by an factual evidence.